K001441

DEC 1 8 2000

LifeScan Saturn Blood Glucose Monitoring Test Strip
510(k) Premarket Notification

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, and Contact Person

LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312
Phone: (408) 263-9789
Facsimile: (408) 942-5906

Contact Person: Mary Ellen Holden
Sr. Regulatory Affairs Specialist

Date Prepared: May 4, 2000

Name of Device and Name/Address of Sponsor

Trade name: Saturn Blood Glucose Monitoring Test Strip

LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312

Classification Names:

Glucose oxidase, glucose test system (21 C.F.R. § 862.1345) (75CGA)

Predicate Devices

1. Boehringer Mannheim Chemstrip bG Reagent Strip (K904292)
2. Miles Laboratories Glucostix Reagent Strip (K851703)

Intended Use/Indications

The Saturn Test Strip is a visually read, semi-quantitative test to monitor blood glucose (sugar) levels. The test sample is fresh capillary or venous whole blood. The test is used as an aid in the monitoring and control of diabetes.

- The Saturn Test Strip is not for use in the diagnosis of diabetes.
- It is not to be used as a primary test for maintaining a specific level of blood glucose.
- It is not for use with samples from newborns.

The Saturn Test Strip result is expressed as plasma glucose level. This allows you to compare the result to your laboratory result. Saturn Test Strips are for testing outside the body (*in vitro diagnostic use*).

Device Description

The LifeScan Blood Glucose Monitoring Test Strip is used to measure the amount of glucose in whole blood. When blood is applied to the Saturn Test Strip, reagents in the Test Strip react with the glucose in the blood to produce a color change that is proportional to the glucose concentration. To obtain a result, the user visually matches the intensity of the reacted test strip colors to a color chart. The Saturn Test Strip system consists of the following components: (1) glucose reagent test strip, and (2) color chart.

Principle of Operation

Prior to use, the Saturn Test Strip color windows are examined and compared to the example of an "unused" test strip on the vial label. If either color window of the test strip is darker than the example on the vial label, the user is instructed not to use the test strip. Another test strip or new test strip vial should be utilized.

The user obtains a blood sample using sterile lancet. Approximately 10 - 15 ul of blood is required for accurate blood glucose results. A drop of blood is applied to the white bar between the two blue bands printed on the spreading layer. The blood is then transferred to and absorbed by the two reagent pads. Sample should completely fill the two color windows, but not soak the entire blue spreading layer. The glucose in the blood sample then reacts with the chemistry embedded in the reagent pads to produce a color change. The intensity of the color changes on the color windows is proportional to the concentration of the glucose present in the blood sample. The darker the colors, the higher the glucose concentration in the blood sample.

After 45 seconds the user compares the color windows of the reacted test strip to the color chart on the vial label. The user is instructed not to use test strips from one vial and color charts from another vial. The user selects the glucose level from the color chart that matches the colors on the reacted test strip windows. If the colors on the test strip fall between two examples on the color chart, the user estimates the glucose level between the two closest pairs of color windows.

The Saturn Test Strip provides accurate blood glucose results up to 3 minutes from the time of initial blood sample application.

Data Demonstrating Substantial Equivalence

Performance testing on the Saturn Test Strip demonstrated that the test strip meets the performance requirements for the intended clinical use of the device. Performance Testing was conducted in accordance with FDA's draft guidance, *Review Criteria for Assessment of Portable Blood Glucose Monitoring In-Vitro Diagnostic Devices Using Glucose Oxidase Methodology.* The results demonstrated that the Saturn Test Strip satisfies all performance requirements.

A multicenter clinical study was conducted to evaluate the accuracy of the Saturn Test Strip when used by lay users with diabetes mellitus and by experienced technicians trained in blood glucose testing techniques as compared to a laboratory blood glucose reference test method (YSI). In addition, the Saturn Test Strip was compared to a predicate blood glucose monitoring system. Blood glucose results obtained with the Saturn Test Strip and predicate device were compared to results obtained using the laboratory reference method for measuring blood glucose levels.

The clinical data demonstrates that the performance of the Saturn Test Strip correlates well with the laboratory blood glucose reference test method. When the blood glucose test results were analyzed by the Error Grid Analysis of Clarke et al., the test strip provided results within the range of clinically acceptable accuracy. The data also demonstrates that the Saturn Test Strip's performance is substantially equivalent to that of a predicate device. The clinical data further demonstrate that the Saturn Test Strip performs equivalently in the hands of the diabetic lay user as it does when used by a trained technician.

Conclusion

Performance testing and the Clinical User Study demonstrate that the LifeScan Saturn Blood Glucose Monitoring Test Strip is substantially equivalent to similar legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Mary Ellen Holden
Sr. Regulatory Affairs Specialist
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, California 95035-6312

Re: K001441
Trade Name: Saturn Blood Glucose Monitoring Test Strip
Regulatory Class: II
Product Code: CGA, NBW
Dated: November 7, 2000
Received: November 8, 2000

Dear Ms. Holden:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K001441

Device Name: LifeScan Saturn Blood Glucose Monitoring Test Strip

Indications For Use:

The Saturn Test Strip is a visually read, semi-quantitative test to monitor blood glucose (sugar) levels. The test sample for home use is fresh capillary whole blood. Venous whole blood samples may be used by healthcare professionals. The test is used as an aid in the monitoring and control of diabetes.

The Saturn Test Strip result is expressed as plasma glucose level. This allows you to compare the result to your laboratory result. Saturn Test Strips are for testing outside the body (in vitro diagnostic use).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OTC ☑

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001441